Management of Drug purchasing Storage and Distribution: Manual for Developing Countries. IInd revised edition.

MANAGEMENT OF DRUG PURCHASING, STORAGE AND DISTRIBUTION

Manual for developing countries

Second revised edition

By
Gerd Dörner, E. Merck, Darmstadt
Claus G. Roepnack, M.D., Hoechst AG, Frankfurt/Main
Rolf Burchardt, Bayer AG, Leverkusen
and
FIP Industrial Pharmacists Section

Federation Internationale Pharmaceutique (F.I.P.)

IFPMA
International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

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The Fédération International Pharmaceutique (F.I.P.) and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) consider this Manual as a valuable contribution by pharmacists and pharmaceutical industry to the efforts of the World Health Organization for the Drug Action Programme (DAP) as well as for Primary Health Care. Copies of this Manual can be obtained free of charge from

Fédération Internationale
Pharmaceutique (F.I.P.)
Alexanderstraat 11
2514 JL, The Hague
The Netherlands

International Federation
of Pharmaceutical Manufacturers Associations (IFPMA)
67 rue de St. Jean
1201 Geneva, Switzerland

1. Introduction

Drugs are goods of a special type. Particularly wherever health care services are lacking, drugs have special significance as the first means for the treatment of patients, the relief of pain and the control of diseases.

Within the framework of primary health care, drugs represent a decisive tool in the treatment of basic diseases. Vaccines, especially in vaccination campaigns, provide a decisive preventive measure.

Unprofessional handling of drugs and vaccines during storage and transport are causes whereby they become unusable, especially under extreme climatic conditions.

Drugs cannot be stored forever. Every effort should be made to see that drugs, which often reach their destination at the expense of considerable effort, including financial effort, do remain in good condition and possess their full activity at the time of use.

> Everyone recognizes spoiled food.
> Drugs which are spoiled and which have thus become inactive are only rarely recognized.
> Since even a brief incorrect treatment or storage of drugs can make them inactive under certain circumstances, everyone who has anything to do with drugs has a special responsibility.
> If you were ill, would you wish to receive an inactive drug, or bear the blame for your family members or closest friends receiving such a drug due to your negligence?

The purpose of this manual is to draw attention to the special significance of sensible management of drug purchasing, storage and distribution, and by reference to the many levels of informative material available today, to contribute to the prevention of unnecessary losses in drug dispatch and storage.

This manual was written with a view to providing some information and suggestions regarding this complex topic for all those who are responsible, now and in future, for drug supplies, especially with regard to their storage and distribution. It has been produced with a mind to all interested persons up to the District level who have some knowledge or schooling already. Statements which are considered to be particularily important are indicated separately (boxes) and can be utilized as information sources (posters for example) for junior personnel.

The authors wish to thank all readers and users of the first edition of this Manual, who have contributed to the second edition by sending us their comments and recommendations. This appreciation is specially directed to colleagues from the WHO as well as to Prof. Friebel, Heidelberg.
Gerd Dörner, pharmacist (member of the F.I.P. Industrial Pharmacist's Section),
Claus G. Roepnack, M.D., physician,
Rolf Burchardt.

2. Review of requirements

2.1. Primary Health Care Sector (PHCS)/Drug Selection

To select the drugs needed (according to health level, local diseases

etc.) is the most important task starting Primary Health Care Projects. Experienced medical doctors will give the necessary recommendations.

In planning a project or in reviewing requirements, it is necessary to define clearly the health service sector for which drugs have to be acquired.

- For the Primary Health Care Sector (village health auxiliaries, medical posts, dispensaries, health centres),
- For the secondary level (medium-sized hospitals),
- For the tertiary level (teaching or large hospitals, specialist clinics).

For treatment in the first case, a reduced range of about

- 5–15 basic drugs for Health Posts (depending on training)

and

- 20–40 basic drugs for Health Centres

should suffice.

More drugs may be required according to the development of the Health Care system.

On the other hand, the drugs requirement of a good hospital depends on the degree of specialisation. In this respect the

- National Drug List

can be consulted.

WHO has published a model list of some 250 essential drugs together with guidelines for their selection in the 3rd report of the WHO Expert Committee on the use of essential drugs (TRS 685). The report also contains a model list of 22 drugs for use at the most peripheral PHC level.

It may be necessary to purchase additional drugs, especially required by a hospital, for special cases and for rare diseases. These drugs depend on the specific needs of a country or a region.

Since the selection of the 20–40 basic drugs (including vaccines where required) varies according to the specific needs, no special recommendations will be given here.

There are a number of different lists available from regional WHO offices, state departments, etc.

2.2. Recommendations for ordering and dispensing of drugs

One of the hardest tasks for health experts is to predict, i.e. to plan the quantities of drugs needed. For economic reasons, excessively high stocks should be avoided. On the other hand, a shortage of necessary drugs due to incorrect ordering is just as disadvantageous in the care of the sick.

In planning quantities of required drugs the accepted norms of treatment have to be taken into consideration. This is very important, when planning different dosage forms with maybe varying contents of the active substances!

Drug formularies of Therapeutic Committees could be established to provide necessary guidelines and criteria for drug selection.

Corresponding publications may be available and may be requested from the local Medical Doctors.

It is thus essential to use a number of aids and rules in establishing the optimum quantities as accurately as possible.

What aids are available?

The questioning of experienced experts in the field has already been mentioned. Also, empirical values are generally available concerning how much of given drugs have been previously bought and used in specific geographical areas and even in each individual medical station, etc. Population counts and their geographical distribution as well as morbidity statistics (where available) have to be taken into account for controlled planning.

Depending on the project in question, it has to be determined what health care is to be provided for what areas and which diseases should be particularly considered in each area as well as the type of health services provided.

For planning and ordering the following practice may be used, to maximize drug selection and minimize stock-keeping:

Vital Drugs:

life saving drugs

- (e.g. antimalarials, certain antibiotics, anthelminthics, oral rehydration salts),
- analgesics
- the drugs where a long-term treatment cannot be discontinued abruptly (e.g. corticosteroids),
- and the vaccines for your immunization program.

Essential Drugs:

Against less severe disease, (e.g. certain antiinflammatory drugs, certain antibiotics, dermatological preparations, certain vitamins).

other drugs:

- (e.g. antacids, cough-mixtures)

Ask your Ministry of Health and/or the visiting physician for advice under which category your individual drugs should be placed. Correspondingly determine the minimum stock (safety stock) for the three groups of drugs depending on the lead time between your order and the receipt of the drugs.

The relatively largest stock should be kept for category Vital Drugs, a smaller for category Essential Drugs – neither should fall to zero – and always try to keep a supply of drugs of the last category as well.

Minimum stocks should be kept according to "lead time" (lead time = time between ordering and receipt of goods). A quantity resulting from monthly maximum consumption + lead time should be ordered to overcome any shortage in case of unexpected delays.

Even in small dispensaries it is important to record all stock movements carefully on your Stock Record Cards or Tally Cards.

Also write the minimum and maximum stock on it and the expiry date.

When you have to order new supplies read the useful information given by these cards before you fill the requisition.

If possible, order your drugs in small containers. If you receive bulk containers, transfer a one week supply into smaller containers, carefully labelled including the name, the batch number and the strength of the drug. From there you can dispense to the patients and the remaining stock in the bulk container is protected from humidity and light.

It is advisable to prepack at least some of your drugs into course-of-therapy plastic bags. Add a clearly written standard label and keep them in a clearly labelled container where they are protected from humidity. Ask the visiting physician for advice.

2.3. Pack sizes and shelf-life

Another important point in any review of requirements is to determine the pack sizes required.

In determining the pack sizes it is basically necessary to consider: large packs (e.g. with 5,000–10,000 tablets) are certainly cheaper per tablet, whereas small packs (e.g. containing an amount for the treatment of one patient only) must be more expensive: they are also safer with regard to stability.

This consideration, however, has to be given to whether the repacking from large packs into smaller packs at the dispensary level may, under certain circumstances, lead to higher costs than would the ordering of smaller packs in the first place.

In addition, the safety risk of refilling/repacking has to be considered and particularly where adequate supervision of the worker is not guaranteed.

Special care has to be taken for clear marking of the repacked units as well as for the inclusion of product information leaflets to safeguard an appropriate drug information to the patient in a language understood by him, or at least understood by the literate Health personnel.

Finally, it is also necessary to consider the fact that many drugs have only a limited shelf-life, which may be further shortened under tropical conditions.

Packing suitable for the tropics would be desirable.

The advice of an experienced pharmacist should thus be sought when developing or extending a drug supply system.

2.4. Budgeting and Ordering

When the quantities determined according to the said criteria are checked, it may happen that the available funds are insufficient. It will then be necessary to establish suitable priorities, to delete some products entirely and to reduce the required amounts of others.

Once the appropriate amounts have finally been established for a suitable period of time, the Buying Department can start ordering.

The amounts ordered and the time scale of ordering depend on various factors:

A central Ordering Office, especially when importing from abroad, has to plan over lengthy periods of time (up to one to two years) and so has to plan in correspondingly large quantities.

For regional requirements per District or in the case of Medical Stations in the interior, the shortest-ordering intervals (e.g. one to two months intervals) and smallest amounts are established in order to avoid overstocking of drugs and their consequent inactivation.

Emergency amounts should, however, be taken into account and should, when possible, be kept in the next larger reserve store.

3. Buying / Ordering systems / Payment

3.1. Introduction

Task:

The task of the Buying Department is to provide, in the required amounts and within the required delivery schedule, the drugs which have been requisitioned.

The Buying Department should thereby use its experience to advise the requisitioning body (e.g. Central Medical Stores) with a view to establishing the optimal ordering quantities and dates.

The Buying Department must possess the appropriate specialized qualifications in order to nominate the products required and determine the quantities needed.

As far as possible, continuous supplies should be guaranteed by means of a suitable ordering frequency.

A close cooperation with medical inspectors of the region to be supplied would be advisable.

Nevertheless, the Buying Department must not itself amend previously determined quantities or substitute an ordered product by another without prior discussion and clear approval.

Suitable training of those working in the Buying Department is absolutely essential. Inexperience can lead to excessively high costs and also to inadequate supplies.

General management training courses can be included here.

3.2. Methods

Basically, there are two ways of buying drugs, namely:

a) direct purchase from specified suppliers, and

b) buying by tender.

The choice of method to be used depends on the type and amount of drug needed, as well as on the time available for completion. Both methods are often used simultaneously.

The advantages and disadvantages must be known precisely in order to decide upon one or the other of the possible methods.

3.3. Direct buying

This is the method to choose when the required products are, for example, patented and therefore available only from one manufacturer or his local agent and under his trade mark. Direct buying is also expedient if only small amounts are required of a product which can be obtained from several manufacturers or where requirements have to be met quickly (e.g. bridging purchases pending the arrival of larger orders).

The advantage here is generally a speedy and uncomplicated delivery.

Quality defects are rare since the manufacturer is, in his own interest, keen to sell perfect goods. The price will depend on the quantities supplied and therefore may be higher than when "buying by tender".

3.4. Buying by tender

If large quantities are needed of a known product available from several manufacturers, it is advisable to invite tenders under the generic name of the required drugs – although the provider may use the brand name apart from the generic name as well. The desired products and required quantities are put out to tender so that all the manufacturers concerned can put in a bid. The order often goes to the manufacturer quoting the lowest price. Considerable amounts can be saved in this way in some cases, or alternatively more products can be bought from the funds available. However, there are risks:

This system can have a clear drawback, reported time and time again in practice. With the desire to secure the order by quoting low prices, suppliers necessarily use all means to cut costs, which often means that the product supplied will not exhibit the desired quality and in extreme cases may not even be usable.

There is also often the problem that the quoted products cannot be delivered at all, especially in the case of

dealers who have no manufacturing capacity of their own, as well as with quotations from certain countries.

The order should be placed taking in consideration evidence of quality and not only on account of price.

In any event, care should be taken to ensure that the quality is specified by means of suitable quality requirements at the time of ordering (references to pharmacopoeia qualities). However, it is best to make use of the WHO Certification Scheme:

It is recommended to make use of the WHO Certification Scheme which provides a simple administrative mechanism whereby importing countries can:

a) obtain assurance that a given product has been authorized to be placed on the market in the exporting country, and, if applicable, obtain information on the reasons for a product not being authorized to be placed on the market in the country of export;
b) obtain assurance that a) the manufacturing plant in which the product is produced is subject to inspections at suitable intervals and b) conforms to requirements for good practices in the manufacture and quality control of drugs, as recommended by the World Health Organization;
c) exchange information on the implementation of inspection and controls exercised by the authorities in the exporting country. In the case of serious quality defects in the importing or the exporting country, such information and requests for enquiries may also be exchanged.

Quality control in own laboratories in the respective country obviously represent an added advantage, especially as this can also check the state of drugs routinely found on the market. This test is thus advisable.

3.5. The order

It is advisable for the Buying Department first to get the supplier to submit a written offer (discounts are possible, depending on the quantities!).

The appropriate order can then be given in writing.

All the important details can be entered in a standard form produced for this purpose.

Each drug item should be labelled under its generic name. Labels must be clearly printed in English language and include all essential product data such as name, dosage strength, presentation, quantity contained, manufacturing data including expiry date (if any), batch number, any special usage of storage precautions, name and address of manufacturer, conditions of delivery and payment, method of despatch, etc.

Depending on geographical location, first check which method of transport (sea, air, land) is preferable. It is a known fact that drugs are often exposed to extreme weather conditions during transportation. Care must therefore be taken to ensure that suitable storage conditions are ready for the goods as soon as they arrive. This is critical both on arrival at the ports and with any interim and final storage.

Air freight may be cheaper than sea freight in many cases, especially when interest on capital has to be taken into account during the period of sea passage. It is also safer with respect to drug quality since extreme climatic stress is avoided.

3.6. Other hints

If supplies often go astray on their way to the hospital or to the Medical Posts, or if they arrive very late in the rainy season, there is a proven method for arranging the orders in such a way that one delivery can be missed without interruption of the running of the hospital. This is: when the new order is placed, there should be sufficient stocks available to last for twice the time normally elapsing between the ordering and the receipt of the goods*.

In cases where there are no road connections (for transportation by lorry, etc.) to many end points, it may be necessary to pool the quantities in units such that they can be carried as head packs (see 7. Rationkits).

3.7. Methods of payment / Reinsurance against inferior quality

The respective terms of payment should be taken into account when the price is established:

CIF means: cost, insurance, freight.
the price includes the price of the goods, the insurance and the freight costs.

FOB means: free on board
the price includes the price of the goods and of despatch from the manufacturer to the loading site (i.e. the airport, sea port or river harbour). Everything else, i.e. insurance and freight from the departure site to receipt site must be payed by the purchaser.

In considering the transportation costs, account must be taken not only of transport time but also of transport duration. A faster transportation route allows an earlier receipt, i.e. an earlier utilization.

In this respect, the payment dates on the one hand have to be weighed up against possible climatic stress due to longer transportation time on the other hand.

As mentioned under 3.4 a quality check is sensible. A minimum of information on the quality of imported drugs is the availability of an import certificate as provided for under the WHO Certification Scheme, but this should be completed whenever possible with a batch certificate from the manufacturer and best also by an analytical control of a sample of the product.

4. Drug storage and distribution

4.1. Introduction

The shipment of drugs to countries with extreme climatic conditions (i.e. normally with high temperatures and high atmospheric humidity), especially countries with tropical climates, implies considerable risks in terms of quality safeguards.

This applies particularly when drugs are stored under especially unfavourable conditions, i.e. without suitable protection from sunlight and moisture and without suitable ventilation.

Pharmaceutical industry generally places great value on the production of especially durable products.

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* Source here and later "Medizin in Entwicklungsländern" (Medicine in Developing Countries), oriented preparatory course of doctors at the Universities of Hamburg, Heidelberg and Tübingen (Heidelberg, January 1980).

Delivery is normally made in special tropical packagings.

In buying drugs which are not obtained directly from a qualified manufacturer and with no corresponding quality guarantee there is the danger that offers which appear to be very favourable pricewise relate to old or even out-of-date goods.

It must also be said again here that even the best quality is not proof against the adverse effect of incorrect handling!

The following section therefore gives some hints as to how the risk during storage and transportation can be excluded as far as possible.

4.2. Storage / General

A major proportion of drugs will last well under favourable storage conditions even in countries with tropical climates, unless the packs state anything to the contrary.

However it is recommendable to check the quality of stored drugs at certain intervals.

Unless special storage conditions are stated, it is vital that drugs be stored in a dry, adequately ventilated, shady and cool store room. With high external temperatures drugs are particularly at risk when adequate ventilation is not ensured.

The foundations of a store room should be high enough to remain dry even under extreme rainfall and flood conditions.

The foundations should be laid so that they are as secure as possible against ground water.

The roof should be constructed so that sunlight cannot reach the floor area or foundations.

In areas with constant, intense sunshine, the roof should be well insulated whenever possible. If necessary, consideration should be given to a double or secondary roof such that the wind can pass through the intermediate space (see Fig. 1).

Good, more detailed recommendations concerning the construction of storage buildings may be taken from the WHO publication Public Health Papers, No. 79 (1984):

"Health Care Facility Projects in developing areas":

Planning, implementation and operation on pages 38–48, where very practical hints are given concerning "Construction and Materials".

Storage recommendations and stability characteristics of 33 selected drugs from the WHO model list of essential drugs as well as other useful information can be found in "Stability of Drugs in the Tropics"[1]).

Important:

Static and particularly hot-damp air in the store room without circulation creates poor conditions for the shelf-life of drugs.

Walls with perforated or bored bricks are ideal since they allow air to circulate over the entire wall surface.

Theft and access for children and animals should be prevented by means of suitable grilles and security devices, whereby close-mesh wire netting should be used in addition to prevent the entry of rodents (see Fig. 1).

The time between ordering and delivery of the goods is normally lengthy. For this reason, suitable planning of the storage area is particularly important. In addition, care must be taken to ensure that misuse and theft are prevented. Orderly organization is therefore of importance to ensure trouble-free storekeeping.

[1]) Smallenbroeck, Hans, Gröningen, The Netherlands (1983).

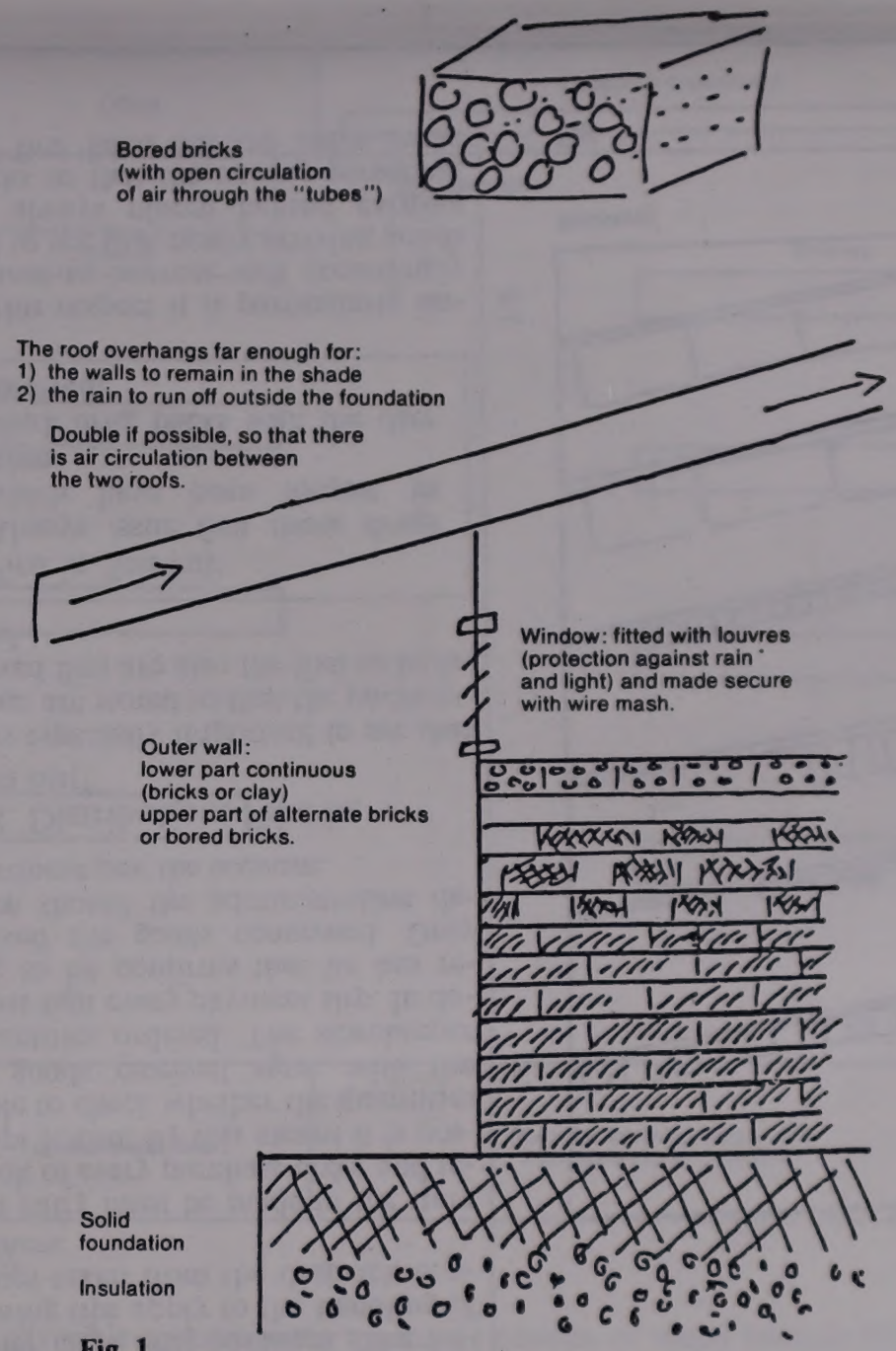

Fig. 1

4.3. Interim storage and miscellaneous

The greatest risk arises in interim storage at airports and seaports as well as at other handling points,

where cases of drugs may be stored in the open, i.e. exposed to the full effects of sunshine, rain and possibly the particularly serious effects of rapidly alternating rain and sunshine (e.g. during the rainy season).

Cases containing high-risk goods, e.g. drugs and especially those in liquid forms, are marked with arrows so that anyone can readily see which way up they should be stacked.

Incorrect storage can, especially with high temperatures, lead to the escape of liquids and so destroy the entire consignment.

Cases which have to be stored dry are marked with umbrellas.

Covering with tarpaulins or plastic sheets provides only a limited protection since not only is the heating by sunshine not prevented, but the lack of ventilation intensifies it.

It has often been observed that inadequate instruction of the workers or inadequate supervision by superiors can have catastrophic effects in this respect.

The greatest care must thus be given to the proper instruction and supervision/control of personnel, and particularly also the constant reminding of the supervisory staff with regard to this need and ensuring that it is met. The importing organization or the forwarding agents must take care to see that the period of interim storage is kept as short as possible.

It is advisable to employ special inspectors responsible for immediate and appropriate storage and handling in harbour and airport facilities.

4.4. Storage points

Where imports are concerned, the considerations mentioned above apply mainly to seaports and airports as well as to the bonded warehouses in them.

However, they also relate in general to all storage points inland, i.e. sea, river and airports, railway depots, central stores and possibly even storage at the wholesalers or other intermediate dealers, and storage in hospitals down to the outlying health stations.

> Never allow cases of drugs to stand in the sun. If this cannot be avoided, cover them up well. It is best to place a sunshade or screen over the cases to prevent sunshine reaching them directly. Store them high up enough on stone slabs or palettes so that puddles do not reach them if it rains. Always stack cases in the way shown by the arrows.

4.5. Inventory record*

In large establishments an inventory record is kept for all wards, offices and, if present, staff accommodation. These records list every shelf, table, chair and other items of furniture. For a house, the employee to whom it is allocated must sign the inventory record on moving in and on moving out. Under certain circumstances, this may apply also to the buildings of medical stations as well as drug stores.

4.6. Issuing of drugs and sending to hospital wards

Experience shows that considerable losses can occur on the route between the drug issuing site and the hospital wards. It is thus necessary to ensure by means of suitable constant checks that the issued drugs do reach the specific destinations within the hospitals.

Both in hospital wards and in medical posts, it is necessary to establish the person who has authority to deliver the required drugs.

4.7. Additional hints concerning storage/bookkeeping

What has been said so far applies to the storage of containers and other large drug packages. The following tips apply to the handling of drugs taken from the despatch containers:

An entry must be made in the store book of every purchase order and receipt issued. By this means it is possible to check whether the quantities of goods received agree with the quantities ordered. The storekeeper must sign every payment slip. In doing so he confirms that he has received the goods concerned. Only then should the administration department pay the account.

4.8. Distribution: First in, first out*

It is especially important to see that drugs are stored so that the packs received first are also the first to be issued.

> First in, first out:
> Always issue first those drugs which have been longest in store.
> Mark drug packs with the date received.

In this respect it is particularly important to instruct staff accordingly and to see that newly arriving goods are always placed behind existing stocks so that the issuing personnel will first hand out the older packs which are at the front. Keep an eye on expiry dates! It is helpful to use shelves with sloping trays (see Fig. 2).

> **Never** place received drugs at the front of the shelves but always at the back so that the goods already present are automatically issued first.

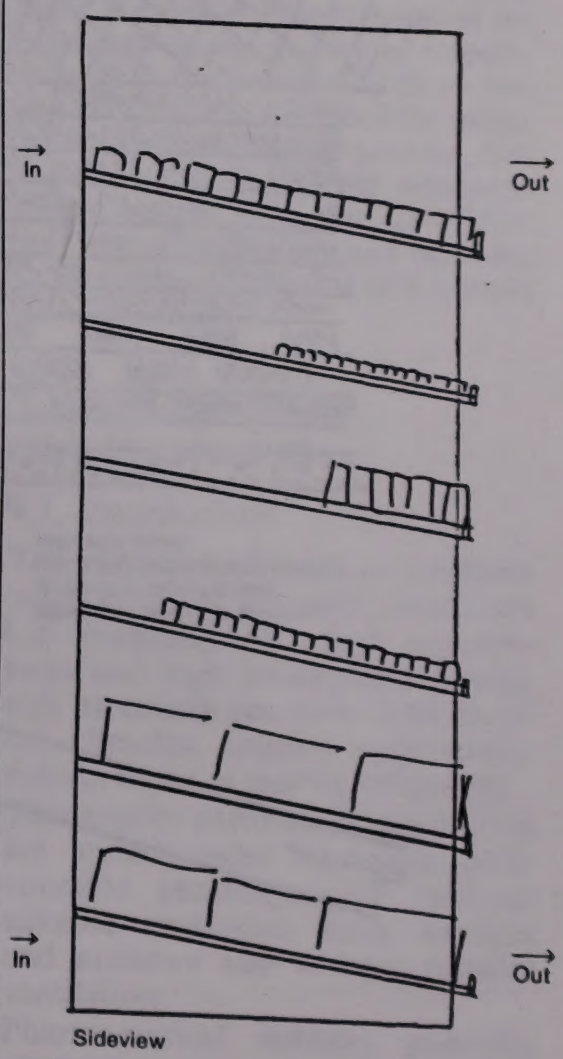

Fig. 2

Depending on the extent of stocks or on the sizes of the individual packages, it is at least worth mentioning the idea of putting a date stamp on incoming packages, or a coloured sticker, in which case a different colour ought to be used for each calendar year (e.g. expiry date marked on the outer pack/lable with a thick felt-tip pen).

> Check the manufacturer's expiry date!
> If the goods will not be used before the expiry date, pass them on early to the nearest central store so that they can be used from there.

Each article should have its own tally card (inventory card) with delivery date, delivery number, completed receipt and the amount of stock remaining. It may be advantageous to record the same data in the store book also (or in an additional card-index system).

4.9. Planning the store room

The following recommendations should be taken into consideration whenever possible in the setting up of stores (including capacity for reception and issue of drugs):

1. There should be no public access to the store room.
2. The drugs should be stored according to some system, preferably in alphabetical order.
3. Only those drugs requiring special storage conditions should be stored separately (narcotics, temperature-sensitive drugs and those which represent a fire hazard). All the others should come to hand systematically in one circuit, e.g. when dealing with combined deliveries.
4. There should be a separate room for the **receipt of deliveries** and for issuing goods to the public.
5. The ideal arrangement of the shelves is such that the drugs to be given out are taken from the front and the replenishment stock is refilled onto the shelves from the back.

Refer to Fig. 3.

4.10. Issue of goods from stores*

In medical stores and hospitals there must be clear rules as to who may make out requisition forms for goods. In principle, the same applies to every site of drug issue, whether large or small.

Stocks are subdivided into:

- consumable articles, such as drugs and bandages, and
- non-consumable articles, such as surgical instruments, car batteries, saucepans, etc.

Very expensive items such as an ambulance or Land Rover can be written off only after examination by a board of survey. Extreme caution is advisable when lending items from the store to private individuals.

4.11. Types of store, supervision*

Depending on the size of the distribution post, there may be various stores such as a drug store, a hospital linen store, a medical equipment store, a furniture store, a building store, a petrol-oil-lubricants-paint store, the "general store" with stationery and electrical goods, and a food store. For Health Posts and Health Centres, only the storage of drugs is relevant.

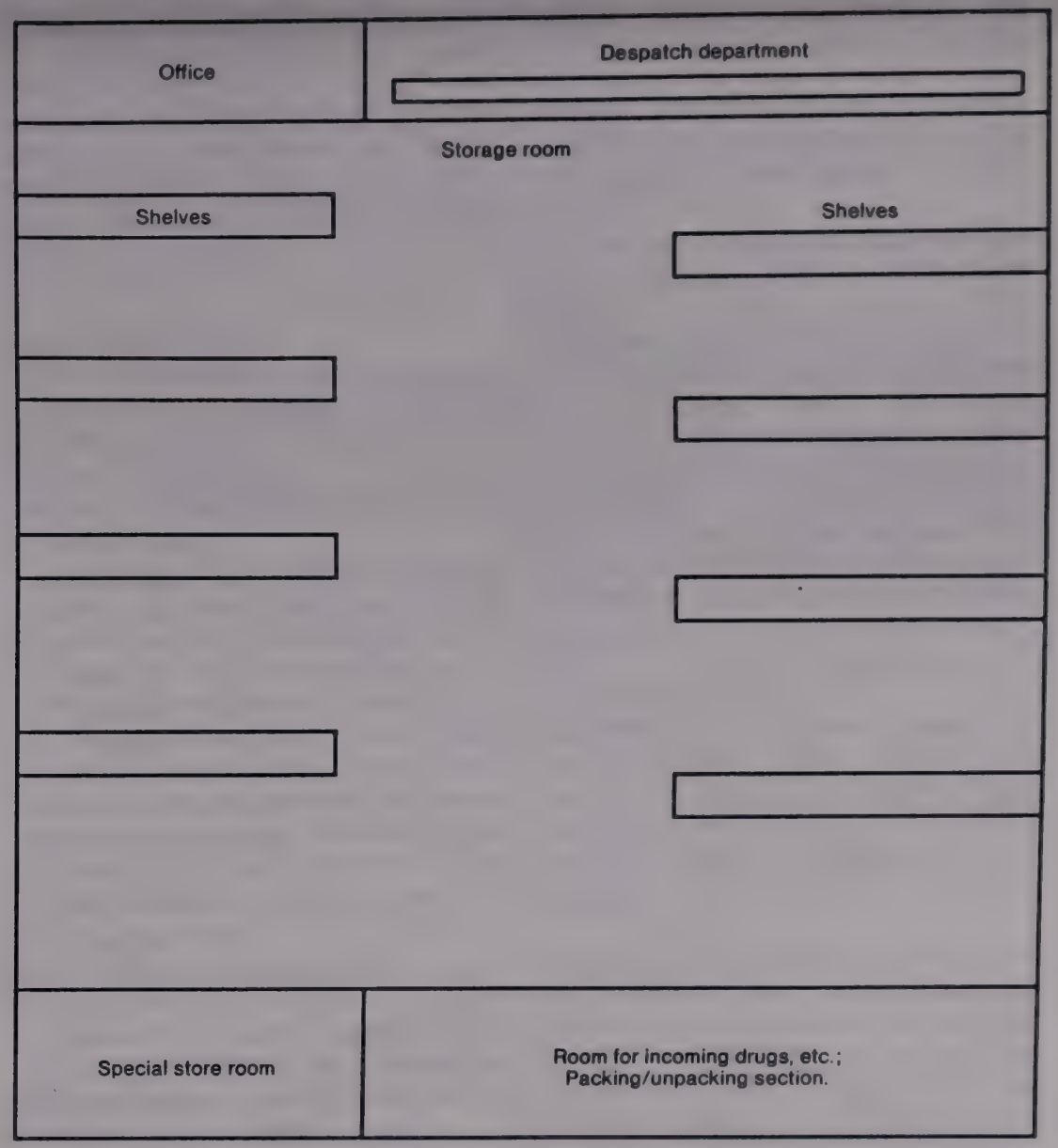

Fig. 3

An advisable precautionary measure is to use a small building at the edge of the hospital grounds as a special store for inflammable goods. All stores should be equipped with fire extinguishers. Where there are fire extinguishers, remember to have their contents renewed at least every two years. A good alternative to fire extinguishers is represented by wooden or metal buckets filled with sand, since sand readily smothers a fire.

The secret of successful supervision of supply stores is to undertake inspections at irregular intervals. A counter-mechanism will soon develop against regular inspections. Surprise inspection is the method of choice. The tricks of stock mainte-

nance are learnt in this way, and more comprehensive checks can be devised for the future.

4.12. More detailed information/ "Good Storage Practice"

The Joint Report of the Fédération Internationale Pharmaceutique (FIP)
- Industrial Pharmacists Section, and of the Committee for Laboratories and Official Drug Control Services of the FIP contains valuable working information for the storage and transportation of drugs (see Appendix 1 and 2).

The guidelines particularly govern:
- What is required of staff, buildings and fittings, including temperature and humidity;
- Hygiene;
- Stores procedure, including written documentation, labelling and supervision of stocks;
- Transportation and despatch.

5. Transport

5.1. Introduction

Despatch from the manufacturer to the country of receipt may be undertaken by lorry, rail, ship or air.

Distribution in the receiving country may be undertaken by the same methods as above, and also by means of other services specific to the country (horses and oxen).

The fastest and therefore the safest method of despatch cannot guarantee the maintenance of the original quality of the drug unless suitable care is applied at each interim store.

5.2. The safest methods of despatch

With regard to international traffic:
air, rail and sea.

With regard to the national traffic:
air,
rail only when (especially in countries with a tropical climate) journey times can be shown by experience not to exceed 36–48 hours.

For these reasons there are many countries in which road transport may be advisable.

However, under certain circumstances it may also be necessary to carry the drugs to their final destination in head packs. This requires that the containers be split into part loads corresponding to the usual weights and sizes for head packs.

5.3. Improving transport and communication

The attached copies from the WHO 1980 Working Guide entitled "The Primary Health Worker" (Appendix 3) gives valuable hints relating to traffic links with remote places, a point vital to the supply of drugs.

5.4. Other hints*

Vehicle fleet

A few hints are quoted from the said Manual*: "The vehicle fleet costs will often be very probably higher than the costs of the drugs. For each amount that has to be spent on buying drugs, a 5–7 times greater amount is required for transportation and distribution! As a direct result of this, suitable control of the vehicle fleet is of particular importance. Hence the following, well proven advice:

a) Each vehicle carries a logbook with columns for date, odometer readings for the start and end of a journey, person responsible for the journey, route, fuel tanked: ... litres, and fuel purchase order number.

b) In general, there should be clear rules stipulating who can give instructions to the drivers.

c) The average fuel consumption for each vehicle should be calculated at the end of each month. If one vehicle has always gone 7 miles to the gallon and suddenly now goes only 4 miles to the gallon, a check becomes necessary.

d) Each vehicle has its own set of tools for which the driver is responsible. The logical principle is "one vehicle, one driver", which helps the drivers to feel really responsible for "their" vehicles.

e) From time to time check the 5 standard items of the vehicles belonging to your responsibility range: FUEL, OIL LEVEL, TYRE PRESSURE, BATTERY, LOGBOOK.

f) Either keep a "Standard Service" book for your vehicles (500, 1000, 5000 miles services), from which you can see whether or not these services have really been carried out, or work out a system whereby one specific week is set aside for each vehicle for servicing. This will prevent the situation of having all the vehicles brought in for servicing at the same time."

Valuable recommendations can be found in the book:

Handbook for Emergencies, Chapter 5, Supplies and Logistics by the UN High Commission for Refugees, Geneva, Dec. 1982.

6. Cold chain

With regard to this topic it should first be established that it is generally not of direct significance for medical stations. Vaccines and sera are generally transported to District Hospital or to special vaccination centres. For this, the cold chain refers to:

the storage and shipping of vaccines and other biological products submitted to "cold chain" conditions (see Appendix 4).

Introduction

In contrast to the majority of pharmaceutical specialities, biological medicines – in particular vaccines – and some diagnostics have to follow different rules as far as packaging, shipping and storing are concerned.

Together with these three factors, another one plays an important role as well: Duration of the stability of the product, its validity or the date of expiration. We therefore have to consider all these aspects as a unity.

Validity

Briefly speaking, validity expresses the period during which the product maintains its full effectiveness – if it has been kept under certain low temperature conditions without interruption.

Packaging

In general, labelling and packaging – which are usually done by the producer – have to follow specific standards outlined in guidelines for the Extended Programme on Immunization by WHO and UNICEF. (Wherever possible, these guidelines should be made use of by national purchasers as a condition of tenders.)

Labels changing colour upon exposure to heat and humidity may be used.

The labels are supposed to show the symbols of a crossed out sun (which means: "No heat, please") or to be

more exact: "keep the materials away from any warmth" ... not only from heat plus a thermometer showing the required range of allowed inside temperature. Furthermore, they read "VACCINES-RUSH".
All this is supposed to make it sufficiently clear that the merchandise is highly perishable.

Storage

When speaking of "storage" in the case of biological products, we actually mean "storage temperature".

ducer a storage between either 0 °C and +4 °C or between +2 °C and +6°C, according to the type of product. Thus, all requirements will be fulfilled.

Due to the thermolability most of the vaccines are permanently sensitive to temperature changes. This makes it necessary to maintain the required storage temperature uninterruptedly.

This fact is being expressed by the denomination "COLD CHAIN".

VACCINE LEVEL: MAXIMUM STORAGE TIME:	CENTRAL STORE up to 8 months	REGIONAL up to 3 months	HEALTH CENTRE up to 1 month	TRANSPORT up to 1 week
MEASLES ORAL POLIO	−15 °C to −25 °C			
DPT TETANUS TOXOID BCG	+4 °C to +8 °C			

Note: Never freeze DPT or TETANUS (which both freeze at temperatures below −3° C). Storage times are recommended maximum figures - remember to check expiry dates (WHO Logistic and Cold Chain for Primary Health Care / How to Store Supplies, No. 2). See page 11.

This storage temperature has to be kept and watched carefully during the whole storage period.
By this – and only by doing it this way – the product can maintain its stability and thus its effectiveness and the validity of the expiration date, as declared by the producer.
In spite of all efforts to unify the storage temperature, several biological products still are submitted to different storage temperatures from others. The following examples may illustrate this:
In order to simplify this variety, it may be recommended by the producer a storage between either 0 °C and +4 °C or between +2 °C and +6°C, according to the type of product. Thus, all requirements will be fulfilled.

It means the maintenance of a uniform temperature level from production to application of the specific product.
The requirements of such a cold chain made it imperative to create some very specific packages and to use special materials for them.
Nevertheless, even if low temperature "batteries" are being used inside the packages as source of energy during the shipment, the prescribed temperature can only be maintained during a very short period (of a few days). The reason for this is the limited energy of these "batteries".

Therefore, the perfect maintenance of an uninterrupted cold chain makes it necessary to handle the merchandise with care and with preference, avoiding any storage in the bright sun or in hot places.
Instead, it should be kept in refrigerators even at airports, in warehouses or hospitals or in cold boxes with low temperature batteries while being transported.
Where there is no electricity available, refrigerators operated with kerosene should be used. Thus, the cold chain from production to application can be safeguarded permanently.
High temperatures – as they are common in tropical regions – are destructive to these products.
Due to this temperature-sensitivity, DPT-vaccine for example, should not exceed a temperature of 30 °C within 48 hours while externally exposed to more than 43 °C – according to specific guidelines issued by WHO and UNICEF.
In the case of the lyophilized vaccine against measles and of liquid poliomyelitis vaccine for oral use, the maximum temperature it may "touch" is even considerably lower "with more than 43 °C outside the package during 48 hours is not supposed to surpass ... 8 °C".
These guidelines have been issued by WHO and UNICEF in order to maintain the effectiveness of the product while being shipped to and handled in countries with tropical climate. Therefore, they have to be observed at any point and at any time of the shipment and storage for the safety of the patient.
A last remark may be added with reference to the expiration date of all biological products: Although any reliable producer will prepare the final product with a certain "margin of security" beyond the date of expiration, the product should not be used after the given date of expiration of its validity – again for the safety of the patient.
Therefore, merchandise with an expiration date should be carefully stored as well with reference to this particular date, following the principle: "Shortest period of validity – first use".
See also the WHO publication "Manage the Cold Chain System" (training for mid-level managers (WHO Expanded Programme on Immunization/October 1980)).
Highly recommended are the WHO publications "Logistics and Cold Chain for Primary Health Care" with the following titles:

1. How to estimate requirements for an existing store.
2. How to store supplies (See page 18).
3. How to distribute supplies.
4. How to keep records and calculate wastage.
5. How to control quality of stocks.
6. How to estimate requirements for the first time.
7. How to estimate chloroquine requirements for the first time.
8. How to estimate ORS packet requirements for the first time.
9. How to estimate vaccine requirements for the first time.
10. How to estimate contraceptiva requirements for the first time.
11. How to estimate essential drug requirements for the first time.
12. The cold chain game.
13. How to improve communication.
14. How to look after a compression refrigerator.

15. User's handbook for compression refrigerators.
16. How to look after a kerosene refrigerator.
17. User's handbook for kerosene refrigerators.
18. How to look after a gas refrigerator.
19. User's handbook for gas refrigerators.
20. How to keep stocks of spare parts.
21. How to look after a cold store.
22. User's handbook for cold stores.
23. Instructors guide.
24. Evaluation questionnaire.

Further information on these booklets can be requested from the Expanded Programme on Immunization, World Health Organization, 1211 Geneva 27, Switzerland.

Additional recommendations are given in "Strengthening the vaccine cold chain" James Cheyne, World Health Forum, 3 (4): 436–440 (1982)

"The most difficult part of a vaccination programme is keeping the vaccine cold during its long journey from factory to vaccinee. Breakdowns are numerous and the consequence can be tragic."

Vaccine Cold Chain Products developed by WHO and Electrolux

In close cooperation between Electrolux and the World Health Organization "Expanded Programme on Immunization" a Cold Chain system has been developed for keeping vaccines continuously at refrigeration temperature.

The products in this Cold Chain have special qualities and special cooling systems, which ensure uninterrupted refrigeration temperature both during storage and transport.

Ice Lining Refrigerator ICW 1151

Large refrigerator/freezer. Ice-lining safe-guarding the vaccine during electrical power failures.

Ice Pack Freezer TFW 790

Freezer with extremely high capacity for freezing Ice Packs. A great number of Ice Packs is needed during the transports.

Vaccine Refrigerator and Ice Pack Freezer RCW 65

Combined Refrigerator/Freezer for storing of vaccines at refrigeration temperature and storing/freezing of Ice Packs. Working on L.P. Gas.

Health Center Refrigerator RCW 42

Small refrigerator with extremely thick insulation. Working on L.P. Gas, kerosene or electricity, net as well as battery.

Insulated Transport RCW 25

Transport box with extremely thick insulation.

According to recent informations (Scrip of 3. 1. 85). a solar-powered chest refrigerator for storing vaccines in hot climates in areas where the electricity supply is unreliable has been developed by Solar Systems Ltd of the UK (a member of the British Petroleum Group of companies) and Lec Refrigeration, for the WHO "Cold Chain".

Any further information referring to the above-mentioned system as well as to any other can be received from WHO, Geneva.

In short:

Some biological products – such as vaccines for example – are highly sensitive to elevated temperatures, as specific and uninterrupted handling under low temperature conditions from production to its application to the patient is required. This is called a "cold chain". The rules of the cold chain are primarily to be observed under tropical conditions in order to guarantee the permanent effectiveness of a sensitive product within a given time and to guarantee its safety to the patient.

A final word concerning misuse of the cold chain: refrigerators and cold boxes are often used for all manner of other items and not just the extremely sensitive vaccines which urgently require their use. Constant instruction and control checks are thus essential.

A vaccine which is stored too warm can suffer a loss of activity within an extremely short time without this being externally detectable. The use of such "vaccine" provides no protection.

> Store and transport vaccines, etc. under the stated temperature conditions.
>
> Any neglect of this requirement can make the vaccine and thus the entire vaccination campaign ineffective.
>
> It depends on your efficacy whether ineffective vaccination can be excluded.

5. Rationkits

Referring to experiences in Nairobi G. D. Moore reported in "World Health Forum", 3 (2), 196–199 (1982) about the Kenyan project of rationkits. Based on a cooperation between WHO, DANIDA and the local government, a system was developed to transport rationkits with medicaments to far removed places to safeguard provision of an adequate supply of the most needed basic drugs of guaranteed quality to all rural health facilities:

"Supplies of drugs to rural areas in Kenya had long been a severe weakness in the nation's health service. Rural health facilities come at the end of long chain starting at the central medical stores and passing through provincial and district hospitals. More often than not, the drugs that arrived at rural health facilities were insufficient or unsuitable. The situation was worsened by problems of pilferage and breakage. Public confidence waned. Rather than wait in vain at a rural health facility with few drugs, patients would walk 20 km or more to the nearest hospital, there to become an additional burden on overworked staff."

"To overcome problems of loss, pilferage, and damage in transit, it was decided to supply the essential drugs to rural health facilities prepacked in sealed boxes, known as rationkits. Each rationkit would be sufficient for the average health facility's needs for one month. The rationkits would be packed at a central facility and shipped out by the central medical stores to rural health facilities via district hospitals, which would serve as depots.

The rural health facilities would then be sure of receiving an adequate amount of the most effective drugs, intact, and on time; in dentation and administrative work at the central medical stores would be greatly simplified; losses in transport or due to rough handling and pilferage could be virtually eliminated;

and rural patients would have a good chance of receiving effective treatment."

8. Quality Control/Quality Assurance Aspect

Quality control, especially with respect to pharmaceutical products, has gained constantly increasing significance in recent years.

Until the early 1960s the quality of drugs was oriented towards the national pharmacopeias. There is no question about the need for extensive quality assurance, which includes the maintenance of quality-related standards in testing and in manufacture. Responsible manufacturers immediately recognized the need for quality control organization to test their products and to provide extensive quality assurance at the individual manufacturing stages. These initiatives were the models for the GMP Regulations of the WHO and for the standards on which national laws have been based.

The main task of quality control is to study the standards for product properties, to evaluate the findings and to reject products that do not meet the standards. It was thus established early (and confirmed in the WHO rules) that, to ensure objectivity, the quality control personnel must work completely independently. For organizational reasons also, this has led to separation from other departments in drug producing companies.

The task of a quality laboratory in a developing country is, of course, not limited to the checking of imported drugs. It should also assure the quality of locally produced drugs by spot testing and periodic supervision to ensure the maintenance of the WHO standards of Good Manufacturing Practices (GMP) in the local factories.

The range of quality control activities has extended far beyond the undertaking of spot checks during the manufacturing process. These activities also include checks to ensure the maintenance of specified "inprocess controls" to achieve the highest possible product quality. The complete monitoring of processes, from the exclusion of errors in manufacture to the checking that finished drugs meet the requirements of set standards, is included in the term "Quality Assurance".

Thus, consignments may become unusable, especially since the raw materials and drugs are not supervised during the transportation time from the manufacturer to the customer. The maintenance of storage conditions during transportation and by the recipient has a decisive influence on shelf-life (i.e. the maintenance of complete efficacy).

Apart from relying on responsible quality assurance by the manufacturer, all importing countries can make use of the Certification Scheme sponsored by the WHO.

Drugs from well-known manufacturers also have the additional advantage that the manufacturer not only ensures the quality on delivery but can also guarantee "after-sales service" (product information concerning action and side-effects as well as stability).

With products of this type, the local quality control tests can be concentrated on spot tests for identity checks and especially on testing for the maintenance of any specified storage conditions.

In the case of active agents and drugs bought "at a particularly good price", the presence of the required quality should be checked particularly critically.

Products to be tested can be roughly divided into categories according to their origin, and this can be the basis for determining the extent of testing by a local laboratory:

- Spot samples for identity and external integrity in the case of products supplied under recognized and binding certificates can allow uneconomic multiple testing to be avoided.
- More extensive testing in the case of products from sources where the maintenance of quality ensuring standards is doubtful, is to be recommended.

Since expertise and product knowledge ist often limited at first, it seems advisable to start with basic analysis which can, with simple materials and methods, detect drugs not conforming to quality requirements. Safety would increase with increasing personal expertise in evaluation.

Basic analysis with negative results, which initially exclude the affected product from use, can subsequently be confirmed or corrected in a well equipped and experienced contract laboratory.

9. Personnel Selection and Guidance

Any technical and organisational recommendation – no matter how good – will remain unsuccessful, unless appropriate

Personnel Selection,
Personnel Guidance and
Personnel Management

ensure that the objectives set are realised and adequate continuity is maintained for the work found to be necessary.

This implies without any doubt the continuous supervision at each level. It must be made very clear at each level of responsibility that no continuous results can be achieved without safeguarding this.

For the purpose of selection, work objectives / job descriptions corresponding to the relevant conditions need to be established so that – based upon these – the necessary preconditions (education, practical experience, general aptitude, previous knowledge required, etc.) can be defined.

In many cases, depending on the size of problem, the services of consultancy firms can be called upon.

Verification of data, certain aptitude tests, assessment of an applicant by several experts – who should not be related to the applicant – are useful aids.

Wherever possible, a trial period should be agreed. Only after this period has been satisfactorily completed, should a firm appointment be made.

For the guidance of personnel, it is important that job descriptions are as precise as possible and are discussed with the applicant or the person appointed.

For the details of a job description and its implementation, the WHO publication

'On being in charge'
A guide for middle-level management in primary health care (1980)

gives excellent guidance and should – initially by senior staff – be carefully studied.

Individual tasks may be allocated to a newly appointed person. The suc-

cess of the work will be decided by appropriate personnel guidance – which must comprise the necessary direction, supervision and motivation – and without the continuity of which no task can be carried out satisfactorily in the long run.
Here appropriate assistance and advice by those experienced in personnel guidance are required.

10. Miscellaneous

10. 1. Handing-over notes*

are notes and documents which each responsible person prepares at set intervals for his supervisors or which he prepares at the end of his period of service as information and recommendations for his successor. These handing-over notes are, for example, part of the standard administrative work of every State hospital.
If these notes are not required, consideration should be given to how far their introduction would be sensible.

10.2. Fire protection*

Adequate measures to ensure fire protection are important for drug stores, especially when readily inflammable liquids are also kept in the store.
When the time comes to renew the contents of fire extinguishers it is a good idea to use the existing contents of the extinguishers for a fire-fighting practice. The opportunity can also be taken to draw up a plan of what to do if a fire breaks out. Who gives the alarm, and to whom? Who looks after any patients? Who rescues the ambulances and other vehicles? Who tries to save the contents of the stores? Who rescues the records and documents?

10.3. Supervision outside normal working hours*

Has the nightwatchman or guard clear instructions (which should be called to mind from time to time) as to what to do in an emergency, in case of fire, accident or theft? Whom should he notify, and in what order? Who holds the keys and where can that person be found?

10.4. Storage of poisons and narcotics (Dangerous Drug Storage/DDS)

Wherever poisons and/or narcotics are stored in drug stores, care must be taken to ensure strict observance of national storage regulations, and their observance must be checked continuously.

11. Concluding remarks

The manual is based on suggestions made by experts from various European companies[2]) who wish, by this means, to contribute to the improvement of drug safety and distribution. The suggestions have been collated essentially by pharmacists of the Industrial Pharmacists Section of the Fédération Internationale Pharmaceutique (F.I.P.: International Pharmaceutical Federation), whereby special thanks are due for the advice given by various medical development agencies such as the Deutsches Institut für ärztliche Mission (DIFÄM: German Institute for Medical Missions), the MISEREOR agency of the Catholic Church, the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ: German Society for Technical Cooperation) as well as MEDEOR and Prof. Diesfeld of Heidelberg, whom we thank for all the notes marked with an asterisk.

[2]) Astra, Bayer, Ciba-Geigy, Hoechst, Hoffmann-LaRoche, E. Merck, Rhône-Poulenc Santé, Roussel Uclaf, Sandoz, The Wellcome Foundation.

A number of publications are now available for advising anyone who needs detailed explanations regarding the complex questions of drug storage and distribution.
The most extensive of these is a co-operative publication of the WHO and Management Sciences for Health (USA), entitled "Managing Drug Supply". In 590 pages this book deals with all the necessary facets to the last detail.
The already mentioned book "On being in charge", published by the WHO in 1980, is also to be recommended, giving in a more readily surveyed form some particular hints concerning planning functions and management of equipment and drugs, together with the problems of transportation routes. Apart from the explanations, this book also has sections with practical exercises.
Hints regarding storage temperatures to be considered for drugs can be obtained from the publication

The Storage of Drugs under Controlled Temperature Conditions

published by the Cleveland Area Health Authority and available from

The Pharmaceutical Department
North Tees General Hospital
Hardwick Estate,
Stockton-on-Tees
Cleveland TS 19 8 PE (UK)

Medical Assistant's Manual (a guide to diagnosis and treatment), McGraw-Hill, Int. Health Services Series, Singapore 1973
Pharmacology and Therapeutics, I.A.T. Mtulia, Rural Health Series 5, African Medical + Research Foundation, Tanzania 1977
Primary Health Care Programme, Southern Region Sudan, Khartum 1976
How to look after a Health Centre Store (Building, Layout, Equipment, Managing supplies); Antony Battersby.
Appropriate Health Resources and Technologies Action Group Ltd., London.
Drug Information Sheets for Use of the Community Health Worker WHO, EMRO 1983.
Handbook for Detailers and Wholesalers Miss Casey, UNICEF, Box 1187, Kathmandu/Nepal.
Manual for Rural Health Workers Management System of Drug Supplies to Rural Health Facilities, Ministry of Health, Nairobi 1984.
Nécessaire d'urgence de l'O.M.S. assortiment standard de médicaments et autres fournitures médicales pour 100,000 personnes pendant 3 mois, O.M.S., Genève 1984
Médecine Tropicale, Marc Gentilini, Flammarion, Paris 1982.

For the authors: Gerd Dörner, pharmacist, Am Elfengrund 19, D-6100 Darmstadt (Federal Republic of Germany)

Good Storage Practice

The Industrial Pharmacists' Selection and the Committee for Control Laboratories and Official Drug-Testing Units of the Fédération Internationale Pharmaceutique (FIP) submitted to the General Meeting of the FIP in Madrid, in September 1980, a joint report on "Good Storage Practice", which is reproduced below. The General Meeting adopted these recommendations and recommended their application.

The recommendations are oriented towards the Good Manufacturing Practice (GMP) Guidelines of the World Health Organization (WHO), i.e. they propose in detailed form and over a wide area some measures to be adopted for GMP Guidelines which cover the storage and transport of drugs and raw materials used in drug manufacture.

They serve not only as the basis for suitable measures on the part of drug manufacturers, but can also be used by drug importers and pharmaceutical wholesalers.

It gives an introductory explanation of the terms of materials, starting materials, intermediate products, packaging materials and finished products, which essentially cover the corresponding definitions approved in the Federal Republic of Germany by the "Drugs, Pharmacy and Poisons" Board of the Arbeitsgemeinschaft der Leitenden Medizinalbeamten der Länder (AGLMB) (Bundesgesundheitsblatt **23**, 46 [1980]).

"Good Storage Practice" is another stone in the edifice of GCP (Good Clearing Practice), GLP (Good Laboratory Practice) and GMP (Good Manufacturing Practice), representing proof of the responsible attitude of the pharmaceutical industry towards its products, and is a guarantee that the patient will receive only finished drugs of high quality.

Pharm. Ind. **42**, 1082–1085 (1980).

Good Storage Practice

"This General Assembly of the Fédération Internationale Pharmaceutique

- Recognises that the safety and quality of medical products are dependent upon the observance of good manufacturing practices.
- Recognises that WHO and national authorities have taken active steps to encourage the adoption and observance of good manufacturing practices.
- Draws attention to the importance of storage procedures in good manufacturing practice and to the observance of correct storage procedures in the distribution of medicinal products by importers, wholesalers and pharmacists.
- Welcomes the publication of a report on 'Good Storage Practice' prepared jointly by the Committee for Laboratories and Official Drug Control Services and the Section of Industrial Pharmacists of F.I.P.
- Commends the report and the implementation of its recommendations to all persons concerned with the manufacture, storage and distribution of medicinal products."

Joint Report of the Committee for Laboratories and Official Drug Control Services and the Industrial Pharmacists Section of the Fédération Internationale Pharmaceutique (F.I.P.):

1. General Considerations

The requirements of the WHO (WHO No. 2865) 25th Report, Technical Report Series No. 567, Geneva 1975, demand a comprehensive control of the manufacture of medicinal products in order to ensure that the consumer receives only finished products of high quality.

The objective of "Good Storage Practice" is to supplement the above mentioned document by elaborating the special measures considered appropriate for the storage and transportation of starting materials and of products at all stages of manufacture, such that the finished product will be of the nature and quality intended when it ultimately reaches the consumer.

The basic principles outlined should be considered as general guidelines; however, where necessary they may be adapted to meet individual needs, provided the desired standards of quality are still achieved.

The guidelines are applicable not just to manufacturers of medicinal products but also to pharmaceutical importers, contractors and wholesalers.

2. Glossary of some terms used

Storage

The term used to describe the safe keeping of starting materials and packaging materials and components received into the factory, semifinished products awaiting despatch. Storage requires the introduction of suitable documentary systems including the maintenance of comprehensive records of receipts and issues.

Material

A summary term covering starting materials, intermediate products, packaging materials and components and finished products.

Starting material

Any substance used in the manufacture of a medicinal product excluding packaging materials.

Intermediate product

A partly processed material which must undergo further processing before it becomes a finished product.

Packing material

Any material used in the packaging of a product. It does not normally include the outer packaging or transit cases used for departmental transportation or shipment of orders.

a) Primary packaging material
   A packaging material which is in direct contact with the medicinal product.
b) Printed packaging material
   A packaging material which is imprinted with a text.

Finished product

A medicinal product which has completed all stages of manufacture, including packaging.

3. Personnel

Key stores personnel who carry out supervisory and/or controlling functions should possess the necessary integrity, knowledge and experience; and where required by national regulations, the professional and technical qualifications appropriate to the tasks assigned to them.

4. Premises and facilities

Premises and other areas to be utilised for storage purposes should comply with prescribed minimum standards.

4.1. They should be constructed, serviced and maintained so as to protect the stored materials, from:
all potentially harmful influences, such as undue variations of temperature and humidity;
dust and odour;
entry of animals, vermin and insects.

4.2. The storage areas should be sufficiently large, and if necessary, should have physically separated zones so that orderly segregated storage is possible.

4.3. Special precautions should be taken for the storage of hazardous, sensitive and dangerous materials such as: combustible liquids and solids;
pressurised gases;
narcotics and other potent habit-forming substances;
highly toxic substances;
radioactive materials;
herbal drugs and remedies.

4.4. Storage areas should be effectively lit thus permitting all operations to be carried out accurately and safely.

4.5. Materials requiring special storage conditions should be placed in separate areas constructed and equipped to provide the desired conditions taking into consideration either the seasonal climatic variations encountered and/or the national regulations in force.

a) Temperature control
   Wherever possible the following definitions should be adopted, or otherwise should serve for guidance. All temperatures in degrees Celsius.
   Cold place
   The temperature does not exceed 8°.
   Refrigerator
   The temperature is thermostatically controlled to between 2° and 8°.
   Freezer
   The temperature is thermostatically controlled to not higher than –10°.
   Cool place
   The temperature is between 8° an 15°.
   Room temperature
   The temperature is between 15° and 30°.
b) Humidity control
   Materials requiring dry or humidity controlled storage should be stored in areas where the relative humidity and temperature is maintained within prescribed limits.

4.6. Where controlled environmental storage conditions are required these conditions should be continuously monitored and the appropriate corrective action should be taken where necessary.

4.7. The equipment used for measuring and monitoring should be checked at suitable pre-determined intervals and the results of such checks should be recorded and retained.

4.8. Storage areas where unprotected raw materials or bulk products are handled such as in sampling and dispensing operations, should be separated from other storage areas, and should have the necessary equipment for performing the work as well as adequate facilities for the supply and exhaustion of air.
Appropriate measures should be taken to prevent cross contamination and to provide safe working conditions for personnel.

5. Sanitation

5.1. The storage areas should be clean, free from accumulated waste and from vermin. A written sanitation programme should be available indicating the frequency and methods to be used to clean the premises and areas.

5.2. Personnel who handle exposed materials or products should undergo periodic health checks. Any person with a disease in a communicable form or with open lesions on the

exposed surface of the body must not work in storage areas.

5.3. Personnel employed in storage areas should wear suitable protective or working garments over or in place of street clothing.

6. Storage procedures for storing raw materials, intermediate products and packaging materials

6.1. Written instructions

Written instructions should be available which specify the working methods to be adopted in the warehouse areas. They should describe adequately the storage procedures and define the route of materials and information through the organisation.

6.2. Labelling and containers

All materials should be stored in containers which do not affect adversely the quality of the material and which offer adequate protection from external influences; in some circumstances this could include bacterial contamination.

All containers should be clearly and indelibly labelled with at least the name and/or code of the material and the lot number of the batch. Unauthorised abbreviations, names or codes should not be used.

A written data sheet should exist for each stored material or product indicating recommended storage conditions, any precautions to be observed and shelf life if necessary. Pharmacopoeial requirements and other current national regulations concerning labels and containers should be respected at all times.

6.3. Receipt of incoming materials

Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity, against the relevant purchase order information.

The consignment should be examined for uniformity and if necessary should be subdivided according to supplier's lot numbers should the delivery comprise more than one batch.

In addition, all containers should be carefully inspected for contamination and damage and if necessary they should be cleaned or set aside for further investigation.

Records should be retained for each delivery. They should include the description of the goods, quality, quantity, supplier, supplier's batch number, the date of receipt and assigned batch number. Where national regulations state a period for retention of records this must be observed.

Samples should be taken only by appropriately trained and qualified personnel strictly in accordance with written sampling instructions. The samples should be representative of the batch from which they were taken.

Following sampling goods normally undergo quarantine. Batch segregation should be maintained during quarantine and all subsequent storage.

The recommended product related storage conditions, for example, type of container, temperature, humidity, protection from light etc., should be maintained throughout the period of storage.

Quarantine status can be achieved either through the use of separate storage areas, or by means of documentary or electronic data processing systems.

The method adopted should possess adequate safeguards to prevent uncontrolled or unsatisfactory materials from being used or released. Materials should remain in quarantine status until a written release or rejection is authorised by the department responsible for quality control. Secure measures should be taken to ensure that rejected materials cannot be used and they should be stored separately from other materials whilst awaiting destruction, rework, or return to the supplier.

6.4. Stock rotation and control

Comprehensive records should be maintained showing all receipts and issues of materials according to batch number.

Periodic stock reconcillations should be performed comparing the actual and recorded stocks. In any event, this should be performed when each batch is totally used up.

All significant stock discrepancies should be subjected to investigation as a check against inadvertent mix-ups and wrong issues.

Issues should normally observe the principle of stock rotation (first in – first out) especially where expiry dated materials are concerned.

Partly used containers of materials should be securely reclosed to prevent spoilage and/or contamination during subsequent storage. Damaged containers should not be issued but should be brought to the attention of the organisation responsible for quality control.

6.5. Control of obsolescent and outdated stock

All stocks should be checked regularly for obsolescent and degraded materials. Materials with an expired shelf life should be destroyed unless an extension of shelf life is granted following the satisfactory results or re-analysis. All due precautions should be observed to preclude issue of outdated materials.

7. Storage and transit of finished products

All stored products should be accurately documented particularly with respect to product name and quantity.

The pack integrity should be verified and maintained at all times.

Comprehensive records should be maintained of the receipt and issue of all products.

Finished products should be protected from excessive climatic conditions during storage and transit, such as heat, frost, moisture and direct sunlight. They should be stored separately from other materials in conditions which satisfy the requirements for the product, so that shelf life declaration may be maintained.

Written instructions

Control of outdated stock.

Sections 6.1 and 6.5 shall apply analogously.

8. Returned goods

All returned goods should be placed in quarantine and returned to saleable stock only on the approval of a nominated responsible person following a satisfactory quality re-evaluation.

9. Despatch

The allocation and shipping of products should be made only after the receipt of a written sales order. Rules for despatch procedures should be established depending on the nature of the product and after taking into account any special precautions to be observed. The shipping container should offer adequate protection from all external influences, and should be indelibly and clearly labelled.

Despatch documents should be retained indicating:

Date of despatch.

Customer's name and address.

Product name and quantity sent.

All documentary records should be readily accessible and be kept in a secure place.

Importers should retain records of all imported goods including batch numbers, so as to be able to comply with relevant national regulations.

Authors: A. Altorfer (Switzerland), H. Chalanson (France), J. D. F. Chissell (Great Britain), R. Furtwängler (Switzerland), L. G. Kinnander (Sweden), T. Witschi (Switzerland), K. Wiesenthal (FR Germany)

Appendix 3

Improving Transport and Communication*)

Learning Objectives

At the end of his training, the PHW (Primary Health Worker) should be able to:

1. Recommend a means of transport to enable the villagers to get to town: mule, donkey, horse, cart or bus
2. Make a stretcher
3. Explain the advantages of being able to get to town in a cart pulled by a donkey, a mule or a horse
4. Explain that, to get to town quickly, three things are needed:
   a) a means of transport
   b) someone responsible for the transport (driver)
   c) good paths
5. Ask a health worker in the next village for advice and show him what has been done
6. Ask important people from the town to come to the village to show them what has been done in the village and to ask their advice

Some patients have no transport to get to hospital or health centre, or very few people from the neighbouring town or villages ever come to visit your village.

All recommendations given may also be useful for the transport of Medicaments!

WHAT SHOULD YOU DO?

1. To get to town more quickly
2. To get to your village more easily

1. To get to town more quickly

1.1. What means do you want to use?

1.1.1 The stretcher for carrying sick people. To make a stretcher:

- cut two strong sticks 2 metres long
- push the sticks through two shirts, or fasten creepers between the sticks (see drawing)

1.1.2 A mule, a donkey, a horse:

- ask the village chief to choose an animal which will always be ready to carry a sick person or to pull a cart
- or ask the chief to get the village committee to buy an animal for this purpose

1.1.3 A cart:

- ask the village committee to find a person who can make a cart
- and to find an animal to pull the cart (see 1.1.2)

1.1.4 The bus:

it the bus passes not too far from the village:

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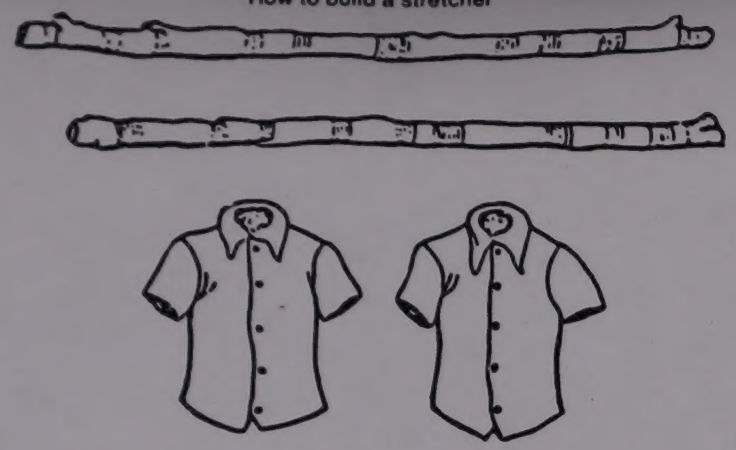
*) This problem also goes beyond the field of health. It is included to prepare PHW's for their role in the development of their communities and to show how much the problems of health and development are linked.

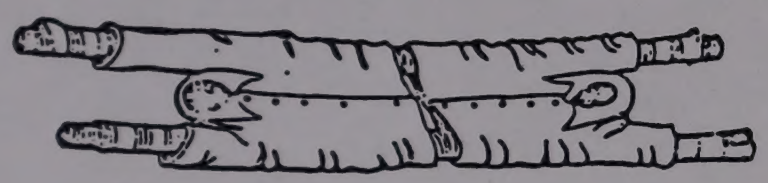
The Primary Health Worker WHO 1980.

According to information from WHO, Geneva, a new, revised edition will by available soon under the title „The Community Health Worker".

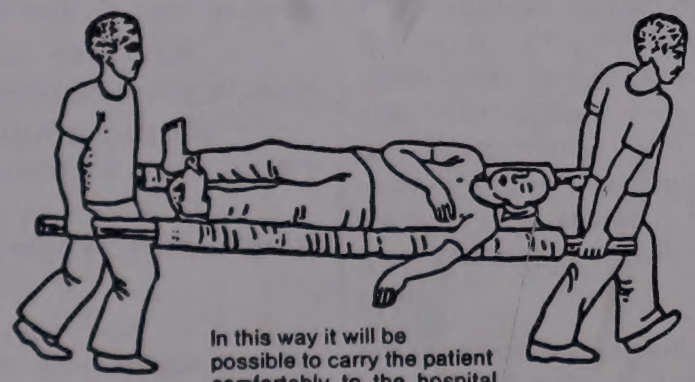
How to build a stretcher



With two sticks 2 metres
and two shirts



Stretcher



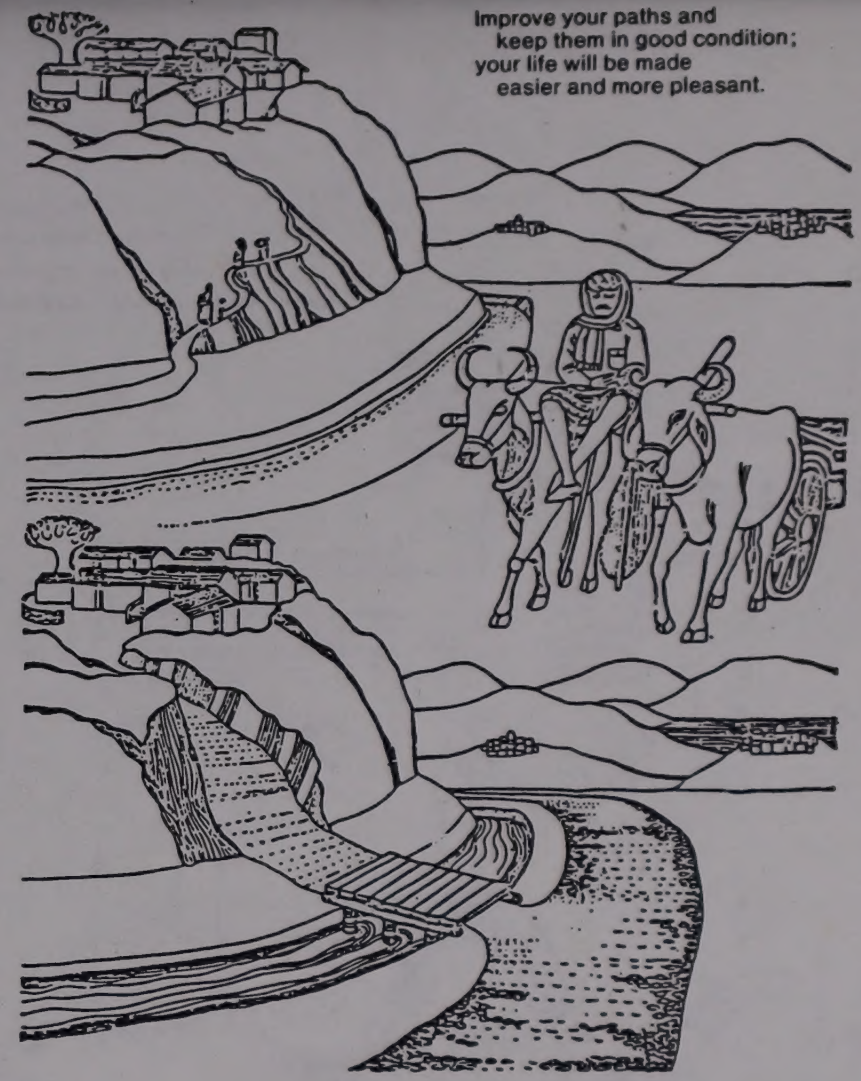
In this way it will be possible to carry the patient comfortably to the hospital or the health centre.

- get the villagers to make a path from the village to the main road
- arrange for the bus to stop at that place

1.2. Who in the village will be responsible for these things?

1.2.1 For the stretcher: ask the chief to choose three people to carry

Improve your paths and
keep them in good condition;
your life will be made
easier and more pleasant.



patients on a stretcher to the hospital or health centre

1.2.2 Ask the chief to choose a driver who will look after the animal and the cart and drive it to town

1.3. Which way will you go?

1.3.1 By the old path:

- ask for the path to be made wide enough to take a cart
- get rid of the weeds, move the stones, fill in the holes
- ask for someone in the village to be chosen to look after the path

1.3.2 By the new path:

- make the path where there are the fewest bumps and holes
- make the path reach the main road as directly as possible
- for the rest, see 1.3.1

Note:

If people can get to town more quickly, not only will patients arrive

at the hospital sooner but also the village people will be able to get to the market more easily, and the people from the town will come and see you more often.

2. To reach your village more easily

2.1 Whom will you invite to come from town?

Your supervisor, the agricultural adviser, the head teacher, the government representative, etc.

For this:

2.1.1 There should be good paths to the village (see 1.3)

2.1.2 They should be asked for advice on improving the village

2.1.3 They should be asked to come and see what you have done

2.1.4 They should be met in town and accompanied to the village

2.2 Whom will you invite to come from the other villages?

The chief or any other important person from a neighbouring village (a teacher, a priest . . .)

For this:

2.2.1 There should be good paths to the other villages

2.2.2 They should be shown what you have done to improve the village, you should ask their advice and ask to visit their village whenever they do something good

Note:

The easier it is to use the tracks or the paths the easier it will be to get to town and to your village.

But good tracks and good paths need some effort.

They must first be made; then they should be kept in good condition and repaired whenever they are damaged.

Appendix 4

The Cold Chain 398 – Prophylaxis of Communicable Diseases

From: Marc Gentilini, Médicine tropicale, 3rd ed., Editions Flammarion, Paris (1982).